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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,880	12/12/2003	John P. Fruehauf	02-1270-A	1031

7590 04/18/2007

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EXAMINER	
YAO, LEI	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,880	FRUEHAUF, JOHN P.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 22-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *exhibit A and B*.

REQUEST FOR CONTINUED EXAMINATION

The request filed on 2/1/07 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10732880 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 1-39 are pending. Claims 1-19 and 22-39 remain withdrawn from consideration. Claims 20 and 21 are under consideration.

Previous final Office Action dated 11/2/06

The rejections in the previous Office action, dated 11/2/06, are withdrawn in view of amendment to the claims.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 2/1/2007 is/are considered by the examiner and initialed copy/copies of the PTO-1449 is/are enclosed.

Specification

Specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 27, line 10, which are improper incorporation by reference. Applicant is required to check entire specification and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim rejections-35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims are vague and indefinite in the recitation of genes of "myosin phosphatase target subunit 1 (MYPT 1), albumin D-box binding protein, complement component 7, plasminogen activator, urokinase receptor, DNA binding protein (HIP 116), zinc finger protein (ZNF 198), or tropomodulin in claim 20. The use of laboratory designations to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. For example, searching for term "HIP116" results in many hits, which have names like "helicase-like transcription factor", "sucrose non-fermenting protein", and "Ring finger protein 80" etc. Each of names has different structure or protein or DNA sequence. This rejection can be obviated by amending the claims to specifically and uniquely identify each of the protein stated above, for example, by SEQ ID NO.

2. Claims are indefinite because the term "DNA binding protein (HIP116) and zinc finger protein (ZNF198) etc. in claim 20 is not clear. It cannot be determined the relationship between the term outside and inside of the parentheses "( )". For example, It cannot be determined "DNA binding protein" comprises "HIP116" or is "HIP116" in the parentheses. However, as broadest interpretation and for the purpose of art anticipation, parentheses ( ) is interpreted as "comprising", that is, term "DNA binding protein (HIP116)" means DNA binding protein comprising HIP 116.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al., (Zhongua Yi Xue Zhi, col 80, page 541-3. July, 2000, abstract).

Claim is drawn to a method for identifying cells or a tumor comprising breast cancer that are resistant to taxane chemotherapeutic drugs comprising steps of determining and comparing the expression of plasminogen activator and identifying increased the expression of the gene in the resistant cells comprising to non-resistant tumor or cell samples. The term cell within the tumor is interpreted as the cells isolated from the tumor sample.

Cheng et al., disclose a method of determining the Taxol resistant cells by overexpression of plasminogen activator by the resistant cells compared to the non-resistant cells. Cheng et al., teach that tissue plasminogen activator is increased expression in the ovarian cancer Taxol resistant cells Skov3/Taxol-25 compared to the Skov3, non resistant cells (abstract).

2. Claims 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Daschner et al., (Breast Cancer Research and Treatment. Vol 53, page 229-240, 1999) as evidenced by Mesh word search for AP-1 protein, c-jun (exhibit A) and description for MCF-7 breast cancer cell (exhibit B).
The set of claims is drawn to a method for identifying cells or a tumor comprising breast cancer that are resistant to taxane chemotherapeutic drugs comprising steps of determining and comparing the expression of DNA binding protein and identifying increased the expression of the gene in the resistant cells, wherein the tumors are breast tumor sample. The term cell within the tumor is interpreted as the cells isolated from the tumor sample.

Daschner et al., disclose overexpression of one of DNA-binding protein, AP-1 component, c-jun (exhibit A), in breast cancer cell, MDR-MCF-7, that is resistant to taxol compared to non resistant cells (page 232, table 1 and figure 1 and 234, col 1). MCF-7 is breast cancer cell line originally isolated from metastatic site of breast adnocarcinoma (exhibit B). As discussed under the 112 2nd rejection, "DNA-binding protein" is not limited to the protein HIP116 in the claim and AP-1 and its components comprising c-jun is a DNA-binding protein and overexpressed in taxol-resistant MDR-MCF-7. Thus, the reference anticipates claimed method.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Exhibit A

- If making selections (e.g., Subheadings, etc.), use the Send to Search Box feature to see PubMed records with those specifications.
- Select PubMed under the Links menu to retrieve all records for the MeSH Term.
- Select NLM MeSH Browser under the Links menu for additional information.

1: Proto-Oncogene Proteins c-jun Links

Cellular DNA-binding proteins encoded by the c-jun genes (GENES, JUN). They are involved in growth-related transcriptional control. There appear to be three distinct functions: dimerization (with c-fos), DNA-binding, and transcriptional activation. Oncogenic transformation can take place by constitutive expression of c-jun.
Year introduced: 1992

Subheadings: This list includes those paired at least once with this heading in MEDLINE and may not reflect current rules for allowable combinations.

☐ administration and dosage ☐ analysis ☐ antagonists and inhibitors ☐ biosynthesis ☐ blood ☐ chemical synthesis ☐ chemistry ☐ classification ☐ deficiency ☐ drug effects ☐ genetics ☐ immunology ☐ isolation and purification ☐ metabolism ☐ pharmacology ☐ physiology ☐ radiation effects ☐ toxicity ☐ ultrastructure

☐ Restrict Search to Major Topic headings only
☐ Do Not Explode this term (i.e., do not include MeSH terms found below this term in the MeSH tree).

Entry Terms:

- Proto Oncogene Proteins c jun
- c-fos-Associated Protein p39
- c fos Associated Protein p39
- c-jun Proteins
- c jun Proteins
- fos-Associated Protein p39
- fos Associated Protein p39
- jun Proto-Oncogene Product p39
- jun Proto Oncogene Product p39
- Proto-Oncogene Proteins jun
- Proto Oncogene Proteins jun

- jun Proto-Oncogene Proteins
- jun Proto Oncogene Proteins
- p39 c-jun
- p39 c jun
- p39(c-jun)
- Proto-Oncogene Products c-jun
- Proto Oncogene Products c jun
- jun B Proteins
- jun D Proteins

Previous Indexing:

- DNA-Binding Proteins (1987-1991)
- Proto-Oncogene Proteins (1987-1991)
- Transcription Factors (1987-1991)

See Also:

- Transcription Factor AP-1

All MeSH Categories
Chemicals and Drugs Category
Amino Acids, Peptides, and Proteins
Proteins
DNA-Binding Proteins
Basic-Leucine Zipper Transcription Factors
Proto-Oncogene Proteins c-jun

All MeSH Categories
Chemicals and Drugs Category
Amino Acids, Peptides, and Proteins
Proteins
Neoplasm Proteins
Oncogene Proteins
Proto-Oncogene Proteins
Proto-Oncogene Proteins c-jun

All MeSH Categories
Chemicals and Drugs Category
Amino Acids, Peptides, and Proteins
Proteins
Nuclear Proteins
Proto-Oncogene Proteins c-jun

All MeSH Categories
Chemicals and Drugs Category
Amino Acids, Peptides, and Proteins
Proteins
Transcription Factors
Basic-Leucine Zipper Transcription Factors

Proto-Oncogene Proteins c-jun

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Exhibit 13

Product Description

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Cell Biology

ATCC® Number:	**HTB-22™** Order this item	**Price:**	**$203.00**
Designations:	MCF7	**Depositors:**	CM McGrath
Biosafety Level:	1	**Shipped:**	frozen
Medium & Serum:	See Propagation	**Growth Properties:**	adherent
Organism:	*Homo sapiens* (human)	**Morphology:**	epithelial

Source: **Organ:** mammary gland; breast
Cell type: epithelial
Disease: adenocarcinoma
Derived from metastatic site: pleural effusion

Cellular Products: insulin-like growth factor binding proteins (IGFBP) BP-2; BP-4; BP-5

Permits/Forms: In addition to the MTA mentioned above, other ATCC and/or regulatory permits may be required for the transfer of this ATCC material. Anyone purchasing ATCC material is ultimately responsible for obtaining the permits. Please click here for information regarding the specific requirements for shipment to your location.

Related Cell Culture Products

Applications:	transfection host (technology from amaxa Roche FuGENE® Transfection Reagents)
Receptors:	estrogen receptor, expressed
Antigen Expression:	Blood Type O; Rh+
DNA Profile (STR):	Amelogenin: X CSF1PO: 10 D13S317: 11 D16S539: 11,12

	D5S818: 11,12 D7S820: 8,9 THO1: 6 TPOX: 9,12 vWA: 14,15
Cytogenetic Analysis:	modal number = 82; range = 66 to 87. The stemline chromosome numbers ranged from hypertriploidy to hypotetraploidy, with the 2S component occurring at 1%. There were 29 to 34 marker chromosomes per S metaphase; 24 to 28 markers occurred in at least 30% of cells, and generally one large submetacentric (M1) and 3 large subtelocentric (M2, M3, and M4) markers were recognizable in over 80% of metaphases. No DM were detected. Chromosome 20 was nullisomic and X was disomic.
Isoenzymes:	AK-1, 1; ES-D, 1-2; G6PD, B; GLO-I, 1-2; PGM1, 1-2; PGM3, 1
Age:	69 years adult
Gender:	female
Ethnicity:	Caucasian
Comments:	The MCF7 line retains several characteristics of differentiated mammary epithelium including ability to process estradiol via cytoplasmic estrogen receptors and the capability of forming domes. The cells express the WNT7B oncogene [PubMed: 8168088]. Contains the Tx-4 oncogene. Growth of MCF7 cells is inhibited by tumor necrosis factor alpha (TNF alpha). Secretion of IGFBP's can be modulated by treatment with anti-estrogens.
Propagation:	**ATCC complete growth medium:** Minimum essential medium (Eagle) with 2 mM L-glutamine and Earle's BSS adjusted to contain 1.5 g/L sodium bicarbonate, 0.1 mM non-essential amino acids and 1 mM sodium pyruvate and supplemented with 0.01 mg/ml bovine insulin, 90%; fetal bovine serum, 10% **Temperature:** 37.0C **Atmosphere:** air, 95%; carbon dioxide (CO2), 5%
Subculturing:	**Protocol:** 1. Remove culture medium to a centrifuge tube. 2. Briefly rinse the cell layer with 0.25% (w/v) Trypsin - 0.53 mM EDTA solution to remove all traces of serum which contains trypsin inhibitor. 3. Add 2.0 to 3.0 ml of Trypsin-EDTA solution to flask and observe cells under an inverted microscope until cell layer is dispersed (usually within 5 to 15 minutes). Note: To avoid clumping do not agitate the cells by hitting or shaking the flask while waiting for the cells to detach. Cells that are difficult to detach may be placed at 37C to facilitate dispersal. 4. Add 6.0 to 8.0 ml of complete growth medium and aspirate cells by gently pipetting. 5. Transfer the cell suspension to the centrifuge tube with the medium and cells from step 1, and centrifuge at approximately 125 x g for 5 to 10 minutes. Discard the supernatant. 6. Resuspend the cell pellet in fresh growth medium. Add appropriate aliquots of the cell suspension to new culture vessels. 7. Incubate cultures at 37C. **Subcultivation ratio:** A subcultivation ratio of 1:3 to 1:6 is recommended **Medium renewal:** 2 to 3 times per week
Preservation:	**Freeze medium:** Complete growth medium supplemented with 5% (v/v) DMSO **Storage temperature:** liquid nitrogen vapor phase
Doubling Time:	29 hrs

Related Products:	Recommended medium (without the additional supplements or serum described under ATCC Medium): ATCC 30-2003 recommended serum: ATCC 30-2020 purified DNA: ATCC HTB-22D 0.25% (w/v) Trypsin - 0.53 mM EDTA in Hank' BSS (w/o Ca++, Mg++): ATCC 30-2101 Cell culture tested DMSO: ATCC 4-X
References:	21405: Sugarman BJ , et al. Recombinant human tumor necrosis factor-alpha: effects on proliferation of normal and transformed cells in vitro. Science 230: 943-945, 1985. PubMed: 3933111 22871: Takahashi K , Suzuki K . Association of insulin-like growth-factor-I-induced DNA synthesis with phosphorylation and nuclear exclusion of p53 in human breast cancer MCF-7 cells. Int. J. Cancer 55: 453-458, 1993. PubMed: 8375929 23046: Brandes LJ , Hermonat MW . Receptor status and subsequent sensitivity of subclones of MCF-7 human breast cancer cells surviving exposure to diethylstilbestrol. Cancer Res. 43: 2831-2835, 1983. PubMed: 6850594 23079: Lan MS , et al. Polypeptide core of a human pancreatic tumor mucin antigen. Cancer Res. 50: 2997-3001, 1990. PubMed: 2334903 23107: Pratt SE , Pollak MN . Estrogen and antiestrogen modulation of MCF7 human breast cancer cell proliferation is associated with specific alterations in accumulation of insulin-like growth factor-binding proteins in conditioned media. Cancer Res. 53: 5193-5198, 1993. PubMed: 7693333 23113: Huguet EL , et al. Differential expression of human Wnt genes 2, 3, 4, and 7B in human breast cell lines and normal and disease states of human breast tissue. Cancer Res. 54: 2615-2621, 1994. PubMed: 8168088 23217: Soule HD , et al. A human cell line from a pleural effusion derived from a breast carcinoma. J. Natl. Cancer Inst. 51: 1409-1416, 1973. PubMed: 4357757 25065: Bellet D , et al. Malignant transformation of nontrophoblastic cells is associated with the expression of chorionic gonadotropin beta genes normally transcribed in trophoblastic cells. Cancer Res. 57: 516-523, 1997. PubMed: 9012484 32275: Littlewood-Evans AJ , et al. The osteoclast-associated protease cathepsin K is expressed in human breast carcinoma. Cancer Res. 57: 5386-5390, 1997. PubMed: 9393764 32278: Komarova EA , et al. Intracellular localization of p53 tumor suppressor protein in gamma-irradiated cells is cell cycle regulated and determined by the nucleus. Cancer Res. 57: 5217-5220, 1997. PubMed: 9393737 32285: van Dijk MA , et al. A functional assay in yeas for the human estrogen receptor displays wild-type and variant estrogen receptor messenger RNAs present in breast carcinoma. Cancer Res. 57: 3478-3485, 1997. PubMed: 9270016 32288: Landers JE , et al. Translational enhancement of mdm2 oncogene expression in human tumor cells containing a stabilized wild-type p53 protein. Cancer Res. 57: 3562-3568, 1997. PubMed: 9270029 32344: Umekita Y , et al. Human prostate tumor growth in athymic mice: inhibition by androgens and stimulation by finasteride. Proc. Natl. Acad. Sci. USA 93: 11802-11807, 1996. PubMed: 8876218 32467: Zamora-Leon SP , et al. Expression of the fructose transporter GLUT5 in human breast cancer. Proc. Natl. Acad. Sci. USA 93: 1847-1852, 1996. PubMed: 8700847 32488: Geiger T , et al. Antitumor activity of a PKC-alpha antisense oligonucleotide in combination with standard chemotherapeutic agents against various human tumors transplanted into nude mice. Anticancer Drug Des. 13: 35-45, 1998. PubMed: 9474241 32547: Jang SI , et al. Activator protein 1 activity is involved in the regulation of the cell type-specific expression from the proximal promoter of the human profilaggrin gene. J. Biol. Chem. 271: 24105-24114, 1996. PubMed: 8798649 32568: Lee JH , et al. The proximal promoter of the human transglutaminase 3 gene. J. Biol. Chem. 271: 4561-4568, 1996. PubMed: 8626812 32582: Chang K , Pastan I . Molecular cloning of mesothelin, a differentiation antigen present on mesothelium, mesotheliomas, and ovarian cancers. Proc. Natl. Acad. Sci. USA 93: 136-140, 1996. PubMed: 8552591 32925: Zhu X , et al. Cell cycle-dependent modulation of telomerase activity in tumor cells. Proc. Natl. Acad. Sci. USA 93: 6091-6095, 1996. PubMed: 8650224 38764: Bacus SS , et al. Differentiation of cultured human breast cancer cells (AU-565 and MCF-7) associated with loss of cell surface HER-2/neu antigen. Mol. Carcinog. 3: 350-362, 1990. PubMed: 1980588

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